Aviagen™

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Dr. Lester Crawford, Acting Director
Food and Drug Administration
5600 Fishers Lane, Rm. 1471
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Rockville, MD 20857

July 22, 2004

Dear Dr. Crawford:

I am writing you on behalf of the Association of Poultry Primary Breeder Veterinarians (see attached membership list) requesting a review of the ruling by the Administrative Law Judge (Judge Davidson) supporting the Center for Veterinary Medicine's request to withdraw the approval of Baytril for use in poultry. Members of our association represent companies that are responsible for the production of more than 80% of the world supply of meat-type chicken, egg-type chicken and turkey breeding stock. As veterinarians we are responsible for the health and welfare of the poultry in our charge, as well as issues related to food safety and public health. We have the additional responsibility of protecting and preserving our companies' irreplaceable breeding stock. Baytril has been, and continues to be the only consistently effective treatment for colibacillosis in poultry. For these reasons our members are extremely concerned about the potential loss of Baytril for use in poultry.

We follow strict rules for the use of any antimicrobial including fluoroquinolones (Baytril). We actively support and practice all initiatives recommended by the American Veterinary Medical Association and American Association of Poultry Pathologists relating to judicious use of antimicrobials to reduce the risk of resistance in food animals. We acknowledge that our compliance and cooperation are very important since we have very few options left to treat sporadic outbreaks of bacterial diseases in our valuable genetic stock. As suppliers of breeding stock to the U.S. and international poultry industries, and as veterinarians, we are committed to using our scientific knowledge and skills for the benefit of the public through the protection of animal health, the relief of animal suffering, and the conservation of livestock resources.

Based on the information presented during the Notice of Hearing (NOH) it appears that the risk to public health from continued prudent use of Baytril is minimal, and that in fact, contributes to a safer food supply. Clearly the issues are complex. We are convinced that a thorough and objective review of all evidence by a panel of scientific and legal experts to determine the true impact on food safety and public health with continued use of Baytril versus withdrawal of the product from the market is necessary.

Sincerely,

Eric L. Jensen, DVM, MAM, Dipl. ACPV
Aviagen North America
President, Association of Poultry Primary Breeder Veterinarians

Cc: Dockets Management Branch, Ref. Docket#00N-1571
Association of Poultry Primary Breeder Veterinarians membership

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Association of Primary Poultry Breeder Veterinarians
June 2004

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

September 29, 2004

Eric L. Jensen, D.V.M., M.A.M., Dipl. A.C.P.V.
Aviagen North America
President
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Dear Dr. Jensen:

Thank you for your letter of July 22 addressed to Dr. Crawford regarding the proposed withdrawal of the approval of enrofloxacin use in poultry. As described below, this matter is now pending before Dr. Crawford.

Under longstanding federal regulations governing the withdrawal of approval of a new animal drug, communications about this proposed withdrawal are not allowed between the Commissioner, officials advising the Office of the Commissioner, and persons outside the Food and Drug Administration (FDA). See Title 21 Code of Federal Regulations, Section 10.55(d)(1) (21 CFR 10.55(d)(1)). Therefore, Dr. Crawford is unable to respond to the specific issues regarding enrofloxacin that you raise in your letter. For your information, under these regulations, a copy of your correspondence and this response must be placed in the FDA docket and served on the participants. See 21 CFR 10.55(d)(3).

However, I am able to provide the following information on the regulatory process for FDA's formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. The FDA's formal hearings are conducted by an administrative law judge under regulations found at 21 CFR part 12. These regulations set out the procedures that FDA must follow when conducting formal hearings.

The Center for Veterinary Medicine (CVM) proposed to withdraw approval of the New Animal Drug Application (NADA) 140-828, pursuant to Section 512(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act. That section requires that a new animal drug must be shown to be safe and effective for its intended uses. On October 31, 2000, CVM published a notice of opportunity for hearing (NOOH) in the *Federal Register*. On November 29, 2000, Bayer filed a request for a hearing. The FDA Commissioner agreed and published a Notice of Hearing on February 20, 2002, in the *Federal Register*.

After submission of documentary evidence, written direct testimony, and joint stipulations by CVM, Bayer Corporation, the sponsor of the animal drug, and non-party participant Animal Health Institute (AHI), an oral hearing for cross-examination of witnesses was held between April 28 and May 7, 2003, with Administrative Law Judge Daniel J. Davidson presiding.

The parties and AHI filed post-hearing briefs and replies in the summer of 2003 and the administrative law judge issued an initial decision on March 16, 2004. The parties have filed exceptions to the initial decision.

A public docket was established at the time the NOOH was published in October 2000. The record of the hearing, which includes the NOOH, referenced scientific studies, briefs, hearing transcripts, the initial decision of the administrative law judge, and subsequent filings by CVM, Bayer, and AHI, can be found in this public docket (Docket No. 2000N-1571).

I hope this information is helpful. Thank you for your interest in this issue.

Sincerely,

LaJuana D. Caldwell

LaJuana D. Caldwell
Director
Office of Executive Secretariat

cc: Dockets Management Branch (HFA-305)